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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/073,463  | 02/11/2002  | Andrey Rzhetsky      | AP34006 070050.1942 | 4349             |
| 21003   | 7590        | 08/09/2005           | EXAMINER            |                  |
| BAKER & BOTTS<br>30 ROCKEFELLER PLAZA<br>NEW YORK, NY 10112 |             |                      | ZEMAN, MARY K       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1631                |                  |
| DATE MAILED: 08/09/2005                                     |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/073,463 | <b>Applicant(s)</b><br>RZHETSKY ET AL. |  |
|                              | <b>Examiner</b><br>Mary K. Zeman     | <b>Art Unit</b><br>1631                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/18/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 17-44 have been renumbered 18-45. 17 claims were originally filed and acted upon. Applicant is encouraged to review their numbering in any future amendment.

Applicant's response, filed 5/18/05 has been entered and considered. Claims 1-17 have been canceled and claims 18-45 are pending and are newly filed.

The IDS filed 5/18/05 has been entered and considered.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because certain figures (submitted 5/18/05) are still difficult or impossible to interpret. Applicant is invited to view the drawings in the PAIR system to see what is difficult to interpret. At least the following figures must be replaced/ revised: Figure 2B (can't tell difference between marks, nor determine what the marks represent) Figure 3 (legend difficult to read/ distinguish) Figure 8 (labels on axes unreadable) Figure 10B (dark photograph/ graph). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

Claim 37 is objected to because of the following informalities: The phrases "wherein said molecules are protein" should read either "wherein said molecules are proteins" or "Wherein said molecule[s] is a [are] protein..." similarly the phrase "said conserved features are protein domain" should be corrected for grammatical consistency within itself and the rest of the claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant argues that the new claims provide a tangible result, and they are directed to methods of practical application. These arguments are not persuasive. Methods which manipulate data must be limited to an application within the practical arts, and provide a concrete, tangible and useful result. The probability figures produced by the rejected claims do not meet these standards. The rejected claims do not comprise any “safe harbor” provisions which would render the process statutory. The rejected claims are not limited to a specific practical application such as monitoring a heartbeat, or seismic wave activity. The rejected claims do not provide a result that is concrete, tangible and useful. The result of the method of the claims is a probability figure which is only relevant in the context of other probability figures, and must be further manipulated and interpreted to be useful. The claims do not require that any specific interactions be output or communicated to the user. Applicant is again pointed to MPEP 2106 for further analysis of these types of claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claims 18-45 are all newly filed claims with multiple new steps, phrases and limitations. Applicant has not pointed to specific basis in the originally filed disclosure for each new claim/limitation and none is apparent. Therefore, these claims are new matter.

For example, in claim 18 step (b), determining a single network probability, was not in the original claims, and no specific basis in the disclosure is pointed to. Similarly step (c) in claim 18, determining a sampling probability, was not originally claimed and no specific basis is identified.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 18, the steps of the method fail to carry out the intent of the preamble. The steps of claim 18 lead to the determination of the highest network probability. This is not an identification of a molecular interaction network. The metes and bounds of the term “molecular interaction network” are unclear. What are the minimum requirements of a “network”? two interacting molecules? What are the metes and bounds of the claimed “biological system”? an ecology? How is a conserved domain identified or defined? What is a “known molecular interaction network” and how does one of skill in the art know about it? How is an “attraction probability “based on” this known network? In step (c) what networks are used to determine the sampling probability- the known networks? The interaction networks? The possible networks? And how does one sample “based on” topology?

In claim 19, the terms “upstream or downstream” are vague and indefinite as to what they mean and how they modify the known or possible networks.

In claims 20-23, 29, 30, 32-35, 39-42 the recitations of equations merely by number render the rejected claims vague and indefinite. These claims do not set forth what the variables are, or how they are to be used in the ultimate goals of the recited methods. “using equation 6 or 14” is not a clear concise limitation that sets forth what one of skill in the art needs to do to meet

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the limitations of the claims. Further, what is the difference if one equation is used instead of the other? Are the data differently interpreted? Does one get differing results? How does this affect the methods of the independent claims?

The metes and bounds of claim 24 are unclear, as it is unclear how to apply an entire statistical technique to the method. Markov Chain Monte Carlo techniques comprise a variety of algorithms utilizing a variety of variable and data, none of which are required or defined. Claim 31 has a similar issue.

Claims 36 and 38 have similar problems as claim 18, as well as the same problems with the citations of equations as the above rejection.

Claims 44 and 45 are vague and indefinite as it is entirely unclear how one is to integrate the “predictive” data manipulations of claim 38 with the “wet” testing steps of claims 44-45. Claim 38 only identifies a probable interaction, not an actual one, and no interactions are confirmed or actually identified. Step a actually only identifies an interaction between “molecules” while step b requires “said proteins”. No specific proteins or molecules are identified, merely probabilities of interactions of conserved features of molecules. No proteins or molecules are made, selected or purified such that they can be contacted with any test compound. Therefore, there is no basis for comparison.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
